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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/056,019	04/07/1998	ELAINE I. TUOMANEN	44158/207989(5853-2)	4774

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EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 12/10/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/056,019

Applicant(s)

TUOMANEN ET AL.

Examiner

Marianne Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 19-38 and 40-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 19.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Examination is resumed in view of the petition to revive the instant application granted 7/16/01 (Paper No. 22). The amendment filed 2/2/01 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments filed 2/2/01 have been fully considered but they are not persuasive.

Election/Restrictions

This application contains claims 19-38 and 40-45 drawn to an invention nonelected with traverse in Paper No. 13. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-18 and 39 are under consideration by the examiner.

Specification

The abstract of the disclosure remains objected to because it contains multiple paragraphs. Correction is required. See MPEP § 608.01(b).

While applicant's response directs removal of the line spaces between the paragraphs, this does not correct the presence of multiple paragraphs.

At least claim 9 still does not recite the appropriate SEQ ID NO.

Appropriate correction is required.

The amendment filed 2/2/01 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter

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into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The reference to SEQ ID NO: 24 added at page 5 with respect to Figure 2A appears to be erroneous. The first sequence (at the top of the Figure) does not appear to correspond to the sequence of SEQ ID NO: 24. Note that the first sequence of the figure begins AVASL whereas SEQ ID NO: 24 begins Glu Asn Glu Gly (ENEG). Applicant is requested to verify that the remaining sequences do in fact correspond to SEQ ID NO: 28-39.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

Claim 1-6, 10-18, and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

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As amended, claim 10 appears to be directed to analogs of fragments, mutants, analogs, and derivatives. There does not appear to be any support for this concept and none has been pointed to in the specification by applicant.

Claims 1, 3, 6, 13, and 14 have been amended to recite "conservative variants." No basis has been pointed to for this limitation and none is apparent. It is noted that claim 5 does not recite "conservative" and that this may have been an oversight. It raises the further question as to whether claim 5 is properly dependent on claim 1 if it broadens what type of variants are encompassed.

Likewise, claims 1, 3, 5-6, 13, and 14 have been amended to recite "active fragments." No basis has been pointed to for this limitation and none is apparent.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides of SEQ ID NO: 24 with tertiary structure produced as set forth on page 64, does not reasonably provide enablement for all polypeptides encompassed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification discloses a method of making a particular N-terminal fragment on page 64; however, the specification does not provide any guidance on how to determine tertiary structure (e.g. X-ray crystallography) or how to identify different tertiary structures encompassed by the claims (folded, unfolded, misfolded). With respect to claim 8, this claim language does not exclude other tertiary structures that the native protein may take under different conditions. In addition binding proteins routinely change tertiary structure upon binding to a ligand. The specification disclosure is directed more to retaining a particular function than retaining a

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particular structure. As such, the specification enables production of the protein which inherently possesses a particular tertiary structure (which is not elaborated upon) but does not enable producing proteins with other unspecified tertiary structures.

Claims 1-18 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 7, and 14 (and dependent claims) have been amended from "comprising" to "--having--". However, "having" is not clearly open or closed language and in the absence of a clear definition in the specification is interpreted as open or comprising. It appears that applicant may have intended "consisting of" by the context of their arguments.

Claims 5-6 are confusing in their dependency upon claim 1. SEQ ID NOS: 7 and 9 are not subsequences of SEQ ID NO: 1 nor do they fully contain SEQ ID NO: 1. It is unclear if applicant is considering them variants or analogs of SEQ ID NO: 1. However, if this was the intent then the claims encompass variants and analogs (and so forth) of variants and analogs (and so forth) which would be new matter. Clarification is requested.

Claim 7 is confusing in reciting "polypeptide exhibits a tertiary structure." All polypeptides exhibit a tertiary structure and so this phrase is either superfluous or the claim does not convey applicant's intent. Claim 8 fails to indicate the conditions defining the structure of the native protein (such as pH and temperature) that the claimed polypeptide's tertiary structure must correspond.

Claim 9 remains confusing as no sequence in Figure 2 has 475 amino acids and no specific sequence in Figure 2 is identified as being the consensus sequence intended. No SEQ ID NO. is referenced. It is noted that the numbering in the sequence listing for each sequence begins at one and may not correspond to any numbered position in a full length protein to which the sequence corresponds.

Claim 12 is confusing in that it is unclear of the claim is directed to any proteolytic digestion product, all proteolytic digestion products, or is further defining the Markush group of claim 1 and is not limited to fragment embodiments.

Claim 39 is being interpreted as being directed to an immunogenic composition and not to a vaccine per se. The intended use language "for use as a vaccine" is not viewed as providing a structural or functional limitation whereas "immunogenic" in the body of the claim is viewed as controlling the intended scope of the composition. An immunogenic amount would not necessarily be the same as that required for a vaccine which by definition must provide a protective effect. If applicant intended otherwise, the claim is unclear. Likewise, claim 1 and dependent claims are being interpreted as being directed to an isolated polypeptide and not a vaccine as "useful in a vaccine" is also intended use language and given no patentable weight. If applicant intended to claim vaccines, this should be made explicit (e.g. "A vaccine comprising an isolated polypeptide...").

Claim Rejections - 35 USC § 102

Claims 1-6, 10-14, and 39 are rejected under 35 U.S.C. 102(a) as being anticipated by Masure et al. (WO 97/41151).

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SEQ ID NO: 25 of Masure et al. is disclosed as the amino acid sequence of a choline binding protein from Streptococcus pneumoniae. The sequence listing identifies it as an N-terminal fragment. The reference discloses fragments and pharmaceutical compositions (including immunogenic vaccines) of the disclosed CBPs. This sequence has two N-terminal methionines. (See at least abstract, page 50, sequence listing, and claims.) SEQ ID NO: 25 has sequence in common with SEQ ID NOS: 1, 3, 7, and 9 of the instant invention and has the motif of SEQ ID NO: 6 (KXXE). The recitation of "having" is interpreted as encompassing inclusion of additional unrelated sequences and/or full length sequences. As such, SEQ ID NO: 25 and the disclosure of Masure et al. properly anticipate the claims at least as mutants or analogs of the named SEQ ID NOS. absent a more specific definition of what these encompass. With respect to claim 13, the reference is silent as to lectin activity and choline binding properties; however, absent evidence to the contrary these properties would be inherent as the structural limitations of the claims have been met.

Claims 1-6, 10-14, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Briles et al. (WO 97/09994).

The protein sequences disclosed by Briles et al. are disclosed as from Streptococcus pneumoniae and include N-terminal fragment. Many have N-terminal methionines. The reference discloses fragments and pharmaceutical compositions (including immunogenic vaccines) of the disclosed proteins. (See at least abstract, claims, and Figures 13, 21, and 22.) These sequences have sequence in common with SEQ ID NOS: 1, 3, 7, and 9 of the instant invention and have the motif of SEQ ID NO: 6 (KXXE). The recitation of "having" is

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interpreted as encompassing inclusion of additional unrelated sequences and/or full length sequences. As such, the disclosure of Briles et al. properly anticipate the claims at least as mutants or analogs of the named SEQ ID NOS. absent a more specific definition of what these encompass. With respect to claim 13, the reference is silent as to lectin activity and choline binding properties; however, absent evidence to the contrary these properties would be inherent as the structural limitations of the claims have been met.

Claims 1, 4, 6, 10-14, 18, and 39 are rejected under 35 U.S.C. 102(a) as being anticipated by Hammerschmidt et al. (Molecular Microbiology, 1997).

The sequence for type 47 in Figure 9 of Hammerschmidt et al. has the motif of SEQ ID NO: 6 (KXXE) and contains SEQ ID NO: 9. The figure description identifies it as an N-terminal fragment with an N-terminal methionine. Compositions in pharmaceutically acceptable carriers are disclosed. (See at least abstract and Figure 9.) The recitation of "having" is interpreted as encompassing inclusion of additional unrelated sequences and/or full length sequences. As such, the disclosure of Hammerschmidt et al. properly anticipate the claims at least as mutants or analogs of the named SEQ ID NO. absent a more specific definition of what these encompass. With respect to claim 13, the reference is silent as to lectin activity and choline binding properties; however, absent evidence to the contrary these properties would be inherent as the structural limitations of the claims have been met.

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Conclusion

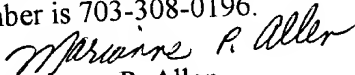
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 7:00 am - 1:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Marianne P. Allen
Primary Examiner
Art Unit 1631

mpa
December 4, 2001